

HPV Vaccine Update and Next Issues for ACIP Consideration

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June 28, 2007



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Outline

- Update
 - Distribution
 - Post-licensure monitoring
 - State legislative action
- Next issues for ACIP consideration

Quadrivalent HPV Vaccine Update

- ACIP recommendation: June 2006
- VFC vote: June 2006
- Provisional recommendations on web: July 2006
- VFC contract: October 2006
- National Injury Compensation Program: February 2007
- ACIP statement in MMWR: March 2007

HPV Vaccine

Distribution and Purchase

- ~5 M doses distributed through March 2007*
 - 49% CDC contract (45% VFC, 2% 317, 2% State)
 - 51% Non CDC
- By April 2007 – all states purchased vaccine for public sector

* Data provided by manufacturer

Monitoring

- Post-Licensure Safety
- Vaccine Coverage
- Disease Impact

Post-Licensure Safety Monitoring

- ISO/CDC
 - VAERS*
 - VSD
- Merck
 - Post marketing MCO study
 - Pregnancy registry
 - ~ 300 women enrolled
 - Annual report – analyzed summer 2007
 - Nordic Cancer Registry

*with FDA

Vaccine Coverage Monitoring

- National Immunization Survey
- National Survey of Children's Health
- National Health Interview Survey
- Immunization Information System Sentinel Sites
- Other projects and surveys
 - VSD
 - BRFSS
 - NHANES
 - NSFG

National Immunization Survey

- Teen Module

- Conducted 4th Q 2006 and will be repeated 4th Q 2007
- First data available July 2007
- Random digit dial telephone survey using national sample of parents of 13-17 year olds (~5000)
- Provider record check for verification of immunizations
- Will be expanded in 2008 to provide state specific estimates

- Adult Module

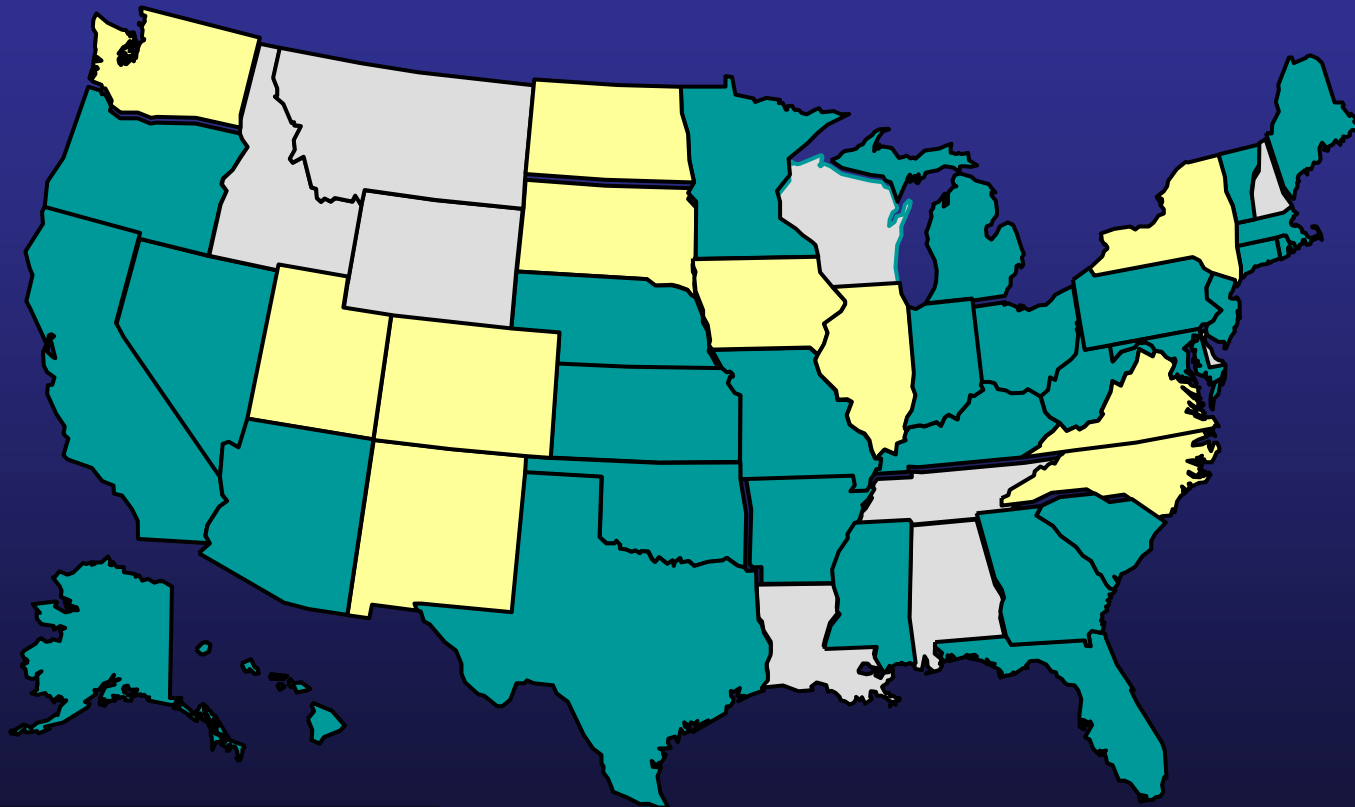
- Conducted May-August 2007
- First data available 4th Q 2007
- Telephone interview of adults 18-49 years
- No provider check for verification

National Survey of Children's Health (NSCH) 2007

- One year data collection - ongoing
- National and state-based estimates
- National sample \approx 92,000 children or \sim 1800 children per state (<18 yrs)
 - Based on parental recall only
- HPV, meningococcal and Td/Tdap questions asked of 12-17 yr olds

State HPV Vaccine Legislation 2007

Education, Funding, or Mandates



As of June 2007

- Introduced
- Signed into law

State HPV Vaccine Legislation 2007

Education, Funding, or Mandates

- >41 states introduced legislation requiring, funding or educating the public about the HPV Vaccine
- >24 states and D.C. introduced legislation specifically to mandate HPV vaccine for school entry
 - Texas - executive order for middle school requirement; overridden by legislature
 - Virginia - passed school HPV vaccine requirement for girls entering 6th grade, with broad exemptions allowed
- North Dakota and New Hampshire – allocated funds to provide vaccine at no cost to females <18 yrs

Overview of Upcoming Issues for ACIP Consideration

- Bivalent HPV vaccine
- Two HPV vaccines on market
- Additional data from quadrivalent and bivalent HPV vaccines trials that may impact recommendations
- Considerations not included in first statement

Bivalent HPV vaccine

- BLA submitted to FDA in March 2007
 - Data included on females 10 - 55 yrs
 - Efficacy study in females 15-25 years
 - Immunobridging studies in younger and older females
 - Timeline for FDA decision
 - 10 month review → January 2008

Bivalent HPV Vaccine

Considerations and Data Needs

- If indicated for currently recommended age groups, need to review
 - Clinical trial data
 - Efficacy
 - Immunogenicity
 - Safety
 - Adjuvant
- If indications for use in older women – need to consider other recommendations
 - Permissive, risk based, no recommendation, other
 - Data to be reviewed
 - Sexual behavior in US (NSFG/NHANES)
 - Natural history and HPV incidence in older women
 - Cost effectiveness
 - Other

Two HPV Vaccines

Considerations and Data Needs

- Preference
 - Differences related to protection against HPV 16/18 and cancer
 - Duration, immunogenicity, cross protection
 - Differences related to protection against HPV 6/11
 - Warts, RRP
 - Cost effectiveness
 - ACIP recommendations for other vaccines
- Interchangeability of doses
 - Theoretical concerns
 - Examples from other vaccines

Ongoing or Planned Studies

	Quadrivalent HPV 6/11/16/18	Bivalent HPV 16/18
Efficacy in females >26 yrs	X	X
Safety & immunogenicity co-administered with adolescent vaccines	X	X
Safety & immunogenicity in HIV+ women (and men)	X	X
Efficacy trials in men 16-26 yrs	X	
Phase 4; long term follow-up	X	X

Ongoing Studies

Quadrivalent Vaccine*

Study Population	N	Data Available	Objectives
24-45 year-old women	3800	Est-3Q 2007	Prevention of persistent HPV 6/11/16/18 infection and disease
16-26 year-old Men	3900	Est-3Q 2008	Prevention of HPV 6/11/16/18 genital lesions and infection
16-26 year-old Men	3900	Est-3Q 2009	Prevention of HPV 6/11/16/18-related anal precancer

*Merck, presented at Feb 2007 ACIP meeting

Est – Estimated (analyses are case-driven)

Estimated Time for Consideration of Other Recommendations

- Older women: If FDA/ACIP requires efficacy data - 2008
- Males - 2009

Considerations not Included in Current ACIP Statement

- Inadvertent administration of vaccine by SC route
- Other special situations

HPV Vaccine ACIP Statement

- Format for Recommendations
 - Separate for bivalent vaccine, or
 - New ACIP statement with information on both vaccines
- Timeline
 - Draft for February 2008

Potential Timeline and ACIP HPV Sessions

June 2007 meeting

- Bivalent HPV vaccine Phase III safety, immunogenicity and efficacy data

October 2007

- Further review of bivalent HPV vaccine data
- Adjuvants
- Update on quadrivalent HPV vaccine data
- Epidemiology of HPV and various HPV-related outcomes
- Discussion of potential recommendations

February 2008

- Cost effectiveness data
- Potential vote on bivalent HPV vaccine, other issues and new ACIP statement

Acknowledgements

CDC

Greg Wallace
Eileen Dunne
James Singleton
Nidhi Jain
Abigail Shefer

Merck

Rick Haupt
Adrian Dana